

REMARKS

Independent claim 1 has been amended; independent claim 25 and dependent claim 26 have been added; and claims 1-4, 6-16 and 21-26 are pending.

Reconsideration and allowance is respectfully requested.

I. Claim amendment objection

Applicant acknowledges the Examiner's objection regarding the claim amendment page, wherein the Examiner stated that Applicant should not include additional text in the heading. The current amendment does not do so.

II. Rejection Under 35 U.S.C 112

The Examiner rejected claim 22 under 35 U.S.C 112 1st paragraph, stating that "there is no support for the combination of conduit resting against the first and the second tissue when the tissues are not part of the same organ." Applicant respectfully disagrees and requests reconsideration.

Figure 7 illustrates sensors 12 placed on opposite sides of a surgical drain 10 positioned between an organ 100 and the surface of a body 102. Paragraph 74 explains that "sensors 12 may be placed on opposite sides . . . of the surgical drain 10 such that the sensor pairs 12a/b may be used to acquire differential measurements between different organs/tissues positioned in the proximity of sensors." Paragraph 74 goes on to give "oxygenation of the liver" as an example of the type of organ against which the surgical drain 10 may be placed. The paragraph explains that differential measurements are helpful in determining whether there may be perfusion problems in

the liver, noting that a low measurement of the oxygen level in the liver alone might be misleading if the body as a whole has the same low oxygenation level. It is inherent that the liver and the body tissue must necessarily rest against the drain in order for these differentials measurements to be made.

Paragraph 82 also explains that the surgical drain may be positioned between the liver and the abdominal wall. It is common knowledge that the liver normally rests against the abdominal wall. Thus, a surgical drain that is inserted between the liver and the abdominal wall – as illustrated in Figure 7 – will necessarily rest against both tissues, as recited in claim 1. Again, the claimed feature is inherent.

Paragraph 114 goes on to state that the surgical drain 10 “may be actively attracted to the surrounding organs/tissue by the continuous negative pressure (suction) in its lumen 32.” In addition, paragraph 0046, lines 10-12 and paragraph 0060 along with figures 3A-3B together specifically teach and show drain holes on opposite sides of the conduit. Therefore, having the negative pressure (suction) being applied to the conduit continuously along with the conduit having drain holes on the opposite sides of the conduit (Figures 3A-3C) makes clear that the opposing tissues may rest against the cannula and that the claimed feature is an inherent feature of the conduit.

Applicant therefore respectfully submits that claim 22 is supported by the original specification.

III. Rejection of claims 1-4, 7-16 and 21-24 under 35 USC 103(a)

The Examiner rejected claims 1-4, 7-16 and 21-24 as being obvious under 35 USC 103(a) in light of Skrabal and Goodman et al. Applicant respectfully disagrees and requests reconsideration.

“To establish a prima facie case of obviousness, . . . the prior art references when combined must teach or suggest all the claim limitations.” M.P.E.P. 2143. This requirement is not met here.

Claim 1 requires “a first sensing element configured to sense a physiological property of the first tissue adjacent to a first location of the elongated conduit; and a second sensing element configured to sense the same physiological property of the second tissue adjacent to a second location of the elongated conduit different than the first location.” (Emphasis added.) In other words, claim 1 requires the same physiological property to be sensed from two different tissue locations. Neither Skrabal nor Goodman et al. disclose this feature.

Even the Examiner admits on page 4 of the office action that Skrabal does not disclose multiple sensors for sensing physiological properties. Further, Skrabal appears to be incapable of sensing physiological properties at different locations. To the contrary, Skrabal withdraws fluid and analyzes the withdrawn fluid as a whole.

Goodman et al. also does not disclose this feature. Indeed, nowhere in the Office Action does the Examiner state that Goodman discloses sensing the same physiological property from two different tissue locations. Although two sets of light sources and photo detectors are disclosed in the “Background of the Invention” section, they are said to “operate at different wavelengths.” Col. 1, lines 48-49. Nothing is disclosed about each

of these sensing a physiological property at a different tissue location, nor even sensing the same physiological property. Nor are either of these claim requirements inherent in what is disclosed. The ECG electrodes (Column 4, line 59 through Column 5, line 2) measure a different physiological property at the same location, exactly opposite of what the claim requires. The suction merely attaches the probe to the fetus's head. This still is not a disclosure of sensing the same physiological property from two different tissue locations.

"To establish a *prima facie* case of obviousness, . . . there must [also] be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings." This requirement is also not met here.

The Examiner states on pages 4-5 of the office action that "one would be motivated to modify the apparatus of Skrabal with the multiple sensors resting against the tissue of Goodman for sensing physiological data for non-invasive way to monitor tissue since the references disclose sensing devices with drains implantable into the body." It is unclear how the Examiner reached this conclusion. Skrabal's objective is to measure the concentration of the substance in the tissue by introducing an exogenous fluid into the needle 2, allowing the fluid to establish substance equilibrium with the surrounding tissue, and then withdrawing the fluid for analysis in an external "analyzing unit 10". Adding Goodman's sensors to Skrabal's needle 2 would not further Skrabal's objective. In fact, Skrabal teaches away from using internal sensors like those disclosed in Goodman by calling them a "disadvantage" and "drawback." See Skrabal Column 1, lines 17-21. The motivation to combine the above references could only be based on

hindsight. The teaching or suggestion to make the claimed combination must be found in the prior art, not applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991) (MPEP 2143).

"To establish a *prima facie* case of obviousness, . . . there must [also] be a reasonable expectation of success." This requirement is also not met here. How would the bulky sensors of Goodman be connected to the needle 2 in Skrabal to measure the same physiological property from two different tissue areas?

In sum, neither Skrabal nor Goodman et al. teach the requirement of claim 1 to sense the same physiological property from two different tissue locations, no motivation has been cited in the prior art for adding the sensors of Goodman et al. to Skrabal, and it does not appear that the bulky sensors of Goodman could be connected to the needle 2 in Skrabal to measure the same physiological property from two different tissue areas. Claim 1 is thus not obvious in view of Skrabal and Goodman et al.

Claims 2-4, 7-16 and 21-24 are dependent upon claim 1 and thus are not obvious in view of Skrabal and Goodman et al. for the same reasons.

Dependent claim 7 also requires a comparison of a difference between the physiological property sensed by the first and second sensing elements. The Examiner alleges that Skrabal discloses this at column 9, lines 59-64. Applicant respectfully disagrees. The cited passage merely states that "a calibrating solution from a container 21 may be delivered to the sensors of the analyzing unit 10 with the use of a pump 23, permitting re-calibration of the sensors before each measurement." This operation is taught to occur "before each measurement." It does not "compare a difference between

the physiological property sensed by the first and second sensing elements,” as required by the language of claim 7.

Dependent claim 23 also requires the first and second sensing elements to be located on the same surface of the elongated conduit. The Examiner admits that this feature is not taught by either Skrabal or Goodman, but nevertheless alleges that it would be an obvious variation. Applicant disagrees and respectfully asks the Examiner to cite prior art that discloses such a feature and a motivation to incorporate it into Skrabal / Goodman or to withdraw this rejection.

The Examiner has rejected claim 6 as being obvious under 35 U.S.C. 103(a) in view of Skrabal, Goodman, Koehn, Santomieri, and Beck. Applicant respectfully disagrees. As explained above in connection with claim 1, neither Skrabal nor Goodman et al. teach the requirement of claim 1 to sense the same physiological property from two different tissue locations; no motivation has been cited in the prior art for adding the sensors of Goodman to Skrabal; and it does not appear that the bulky sensors of Goodman could be connected to the needle 2 in Skrabal to measure the same physiological property from two different tissue areas. Nowhere does the Examiner contend that any of these deficiencies are overcome by Koehn, Santomieri, or Beck. Further, claim 6 requires the sensing elements to be embedded in a conduit configured to be implanted in the patient's body. The sensor 18 in Skrabal, on the other hand, appears to be outside of the patient's body. The Examiner also cites no motivation in the prior art for making this pressure sensor visible during use.

IV. New Claims 25 and 26

New claim 25 and 26 are directed to subject matter that is related to claim 22. New claim 26 is also directed to subject matter related to claim 7. Neither, however, recite the "rest against" feature in claim 22 about which the Examiner interposed an objection. These new claims are also supported by various areas in the specification, such as by Figures 7 and 10-12 and the description of them.

Conclusion

Applicant respectfully submits that this application is now in condition for allowance, which Applicant respectfully solicits.

A Request for Continued Examination and a Petition for a Three-Month Extension of time under 37 C.F.C. 1.136 are being filed contemporaneously herewith. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 501946 and please credit any excess fees to such deposit account and reference attorney docket no. 64693-101.

Respectfully submitted,
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